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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,337	07/14/2006	Akira Nishiyama	Q95734	2433
23373	7590	01/25/2008	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			KELLY, ROBERT M	
			ART UNIT	PAPER NUMBER
			1633	
			MAIL DATE	
			01/25/2008	DELIVERY MODE
			PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/586,337	NISHIYAMA ET AL.	
	Examiner Robert M. Kelly	Art Unit 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 November 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 11 and 12 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3 and 7-10 is/are rejected.
- 7) Claim(s) 1-3 and 7-10 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/14/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

Applicant's response to restriction requirement of 11/16/07 is entered.

Claims 1-12 are presently pending.

### ***Election/Restrictions***

Applicant's election without traverse of Invention I, Claims 1-10, and the species of Candida, encompassed in Claims 1-3 and 7-10 in the reply filed on 11/16/07 is acknowledged.

Claims 4-6 and 11-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/16/07.

Claims 1-3 and 7-10 are presently considered.

### ***Information Disclosure Statement***

It is noted that the information disclosure statement contains two non-english references, and the reference to Whitney 1972 is incomplete. Hence, these references have not been considered and crossed-off the IDS. The balance of the references have been considered, signed, and initialed.

### ***Claim Objections***

Claims 1-3 and 7-10 are objected to because of the following informalities:

Claim 1 is objected to for the various recitations of "represented" and "represents". To wit, each of the formulae may "represent" anything, as long as that is the intent of the person

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making the formulae. However, because the Artisan would understand what is being claimed, no rejection is made for lack of clarity. It is recommended to amend each term to "of the structure", or something similar, and, in the case of "represents", the terminology may be amended to recite "wherein \* is the position of an asymmetric...".

Claim 2 recites that the asymmetrical reduction is produced by the action of an "enzyme source" having the activity. However, it is not the source of the enzyme, but by definition, it is the enzyme itself.

Claims 3 and 7-10 are objected to for depending from objected to base claim(s), and not correcting the problem with the base claim(s).

Claims 2-3 and 7-9 each recite an enzyme source, without actually requiring the source to contain an enzyme, especially in light of Claims 3 and 7-9 which recite in the alternative the enzyme source or the enzyme itself. And hence, it would appear that the source is not necessarily a composition comprising the enzyme, but anything derived from the same source. However, the Artisan would understand what is encompassed, and hence, the claims are not rejected for lack of clarity.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Whitney, et al. (1974)

Advances in Chemistry, Vol. 130: 270-80.

Whitney teaches the reduction of 5-hydroxy-2-pentanone by chelated lithium compounds, to yield optically active 1,4-pentanediol (e.g., p. 277). Hence, the claim is anticipated.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitney, et al. (1974) Advances in Chemistry, Vol. 130: 270-80 and the general knowledge in the art.

With regard to Claim 1, as shown above, Whitney teaches one from of enzymatic reduction of the compound. However, Whitney does not teach obtaining the compound for reduction from a method comprising acid hydrolysis of 2-hydroxy-gamma-butyrolactone.

On the other hand, it is well known that 2-hydroxy-gamma-butyrolactone has been available for years, and even Applicant's specification that the availability of such is superior to other sources, evidencing Applicant's acknowledgement of the Art. This is Official Notice.

Second, it is instantly recognizable to the Artisan, who is aware of organic chemistry, that an acid hydrolysis, followed by a reduction by LiAlH<sub>4</sub> will yield the alcohol of formula 2.

Hence, at the time of the invention, the claimed invention would have been obvious. The Artisan would be motivated to perform the acid hydrolysis to perform a reduction and thereby

obtain the compound of interest. Moreover, the Artisan would have had a reasonable expectation of success, as the art of organic chemistry was already fleshed out for the methods involved in such syntheses.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitney, et al. (1974) Advances in Chemistry, Vol. 130: 270-80; and Wada, et al. (1998) Biosci. Biotechnol. Biochem., 62(2): 280-85.

Whitney teaches the reduction of 5-hydroxy-2-pentanone by chelated lithium compounds, to yield optically active 1,4-pentanediol (e.g., p. 277). Further, Whitney teaches that biological enzymes may also be used to perform similar stereoreductions of the compounds. However, Whitney does not teach the use of an enzyme from, or a compositions comprising the enzyme from, *Candida magnolia*.

On the other hand, Wada teaches the purification and characterization of an NADPH dependent Carbonyl Reductase of *Candida magnolia*, which reduces compounds with a ketone, including many oxobutanoates, pyruvates, diacetyls, ethyl pyruvate, lactones, isatin, and 2,3 pentanediones. From this the Artisan would conclude that the sole structure for this

stereoselective reduction is the presence of the carbonyl group, and that the 1,4 pentanediol of Whitney could be reduced.

Hence, at the time of invention, it would have been obvious to reduce 1,4-pentanedione with the carbonyl reductase of Wada. The Artisan would have been motivated to do so to produce 1,4-pentanediol from 5-hydroxy-2-pentanone. Moreover, the Artisan would have a reasonable expectation of success, as Whitney taught that biological enzymes could be used, and Wada teaches a biological enzyme from *Candida magnolia* which produces the same activity.

### ***Conclusion***

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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